

PATENT COOPERATION TREATY

REC'D 06 JUN 2006

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **01 JUN 2006**

Applicant's or agent's file reference

014811-422

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US05/09325

International filing date (day/month/year)

22 March 2005 (22.03.2005)

Priority date (day/month/year)

23 March 2004 (23.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(8): A61K 31/606, 31/192, 31/194, 31/196 and US Cl.: 514/165, 563, 566, 567

Applicant

NOBEX CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Date of completion of this opinion
17 January 2006 (17.01.2006)

Authorized officer
Phyllis G. Spivack
Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/09325

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/09325

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Industrial applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-31 fail to meet the criteria of PCT Articles 33(2) and 33(3) because the prior art teaches each limitation of the present claims. The present claims lack an inventive step over the prior art. Ekwuribe teaches pharmaceutical compositions comprising APAZA, 5-(4-carboxymethyl-phenylazo)-2-hydroxybenzoic acid, a compound that degrades in the gut following bacterial azo reduction, to 5-aminosalicylic acid (5-ASA) and 4-aminophenyl acetic acid (4-APAA) for the treatment of inflammatory conditions of the gastrointestinal tract. Therefore, the administration of APAZA physiologically equates to the therapeutic administration of two of the required agents recited in instant claim one. Further, see Table 1, page 20, where a mixture of 5-ASA and 4-APAA is disclosed. See page 12, lines 8-12, where optional additional active medicaments may be included in the therapeutic regimen. See pages 10-11 where various dosage forms are disclosed. Administration of an enema, suppository or delayed-release formulations is well known in the prior art where treatment of a gastrointestinal disorder is the therapeutic endpoint.

Claims 1-31 meet the criteria of PCT Article 33(4) as they are directed to pharmaceutical compositions and methods of treatment thereof for inflammatory bowel diseases.